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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,228	07/19/2001	Anna Victoria Hine	PL-9830	7993

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/11/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File Copy*

Application No.

09/787,228

Applicant(s)

HINE ET AL.

Examiner

Jon D Epperson

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-6 and 13 are drawn to a product described as “a set of libraries of genes.”
- II. Claim 7-12 are drawn to a product described as a “a set of library of proteins.”
- III. Claims 14-23 are drawn to a method “of identifying a protein.”
- IV. Claim 24 is drawn to a product described as a protein having SEQ ID NO: 1.
- V. Claim 25 is drawn to a product described as a gene that codes for the SEQ ID NO:1 protein.
- VI. Claims 26-27 are drawn to a method “of constructing randomized gene libraries.”

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

4. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special

Art Unit: 1639

technical features.” It further defines “special technical feature” as “those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art.”

5. Groups I-VI do not share the same technical features. Groups I, II, IV and V are drawn to different products (e.g., they differ in respect to their properties, their use and the synthetic methodology for making them) and Groups III and VI are drawn to different methods (e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods represent distinct subject matter. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics.

6. Groups I, II, IV and V do not share a technical feature because they represent distinct products. For example, Groups I and V are drawn to “gene” products whereas Groups II and IV are drawn to “protein” product. Each nucleic acid is structurally and functionally distinct from each polypeptide. Therefore, Groups I and V do not share a special technical feature with Group II and IV. Likewise Groups I and II are drawn to a “library” whereas Group IV and V are not. The libraries of Groups I and II would not necessarily contain the individual members of Groups IV and V and, as a result, Groups I and II do not share a special technical feature with Groups IV

Art Unit: 1639

and V either. Consequently, Groups I, II, IV and V do not share a special technical feature.

7. In addition, a technical feature does not link the methods of Groups III and VI. The methods do not share a special technical feature because they use different steps, require different reagents and/or will produce different results. In the instant case, Group III requires “proteins” for binding partner “screening” whereas the method of Group IV requires “nucleic acids” for the production of a “gene library” and “gene expression” products. Therefore, Groups III and VI do not share a special technical feature.

8. Furthermore, a technical feature does not link the methods of Groups III and VI with the products of Groups IV and V because the methods of Groups III and VI require a “library” whereas Groups IV and V only disclose a “single” molecule of protein or DNA. Therefore, Groups III-VI do not share a special technical feature.

9. Finally, The technical feature linking Groups I and II with Groups III and VI appears to be that the method steps of Groups III and VI requires the library products of Groups II and VI, respectively.

10. However, Choo et al. (Choo, Y.; Klug, A. “Toward a code for the interactions of zinc fingers with DNA: Selection of randomized fingers displayed on phage” Proc. Natl. Acad. Sci. USA 1994, 91, 1163-1167) teaches the nucleic acid and protein libraries that Applicants claim in Groups I and II. For example, Choo et al discloses a library of nucleic acids (and also the

Art Unit: 1639

proteins that they encode) that contain the sequence ... FSXXXXLXXHX(R/K)THT wherein each X contains a library of codons composed of equal mixtures of (G/A/C)NN at each of the X positions constituting "seven" libraries. Choo also discloses yet another nucleic acid library at the +9 position containing the randomized sequences of A(G/A)G (see Choo et al., figure 1).

11. Consequently, Groups I-III and VI are drawn to different special technical features. For example, Groups I and II are drawn to different products (e.g., they differ in respect to their properties, their use and the synthetic methodology for making them) and Groups III and VI are drawn to different methods (e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics.

12. Therefore, the technical feature linking the inventions of groups I-III and VI does not constitute a species technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

13. Accordingly, groups I-VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Art Unit: 1639

14. Also see MPEP 1850: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By dependent claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression category of claim referring to the classification of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).

15. Finally, see 37 CFR § 1.475 - Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage, cited in part below (especially sections (c) and (d)).

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

A product and a process specially adapted for the manufacture of said product;

or

A product and process of use of said product; or

A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

A process and an apparatus or means specifically designed for carrying out the said process; or

A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

Art Unit: 1639

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

16. The instant application contains multiple products and methods. The first product (i.e., Group I) is not linked with the first method of using said first product (i.e., Group III) because the technical feature that links the Group I with Group III is known in the art, as set forth above. Thus, the instant claims lack unity of invention.

Species Election

17. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked to form a single general inventive concept under PCT Rule 13.1.

18. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species below. Applicant must elect one species from each subgroup below. Claim 1 is generic

Subgroup 1: Species of gene library (see claim 1)

Applicant must elect for purposes of search a single species of gene library that is “representative” i.e., contains the same properties and or structural features as the rest of the library members.

Subgroup 2: Species of protein (see claim 1)

Applicant must elect for purposes of search a single species of protein e.g., zinc finger.

Subgroup 3: Species of library set (see claim 4)

Art Unit: 1639

Applicant must elect for purposes of search a single species of protein e.g. 36 libraries in three groups of 12 libraries that code for amino acids at the -1 and +3 and +6 positions, respectively.

Subgroup 4: Species of encoded protein sequence (see claim 6)

Applicant must elect for purposes of search a single species of protein e.g., SEQ ID NO: 2.

19. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species below. Applicant must elect one species from each subgroup below. Claim 7 is generic

Subgroup 1: Species of protein library (see claim 7)

Applicant must elect for purposes of search a single species of protein library that is "representative" i.e., contains the same properties and or structural features as the rest of the library members.

Subgroup 2: Species of binding partner (see claim 7)

Applicant must elect for purposes of search a single species of binding partner e.g., polynucleotide.

Subgroup 3: Species of library set (see claim 10)

Applicant must elect for purposes of search a single species of protein e.g. 60 libraries in three groups of 20 libraries with specified amino acids at the -1 and +3 and +6 positions respectively.

Subgroup 4: Species of protein sequence (see claim 12)

Applicant must elect for purposes of search a single species of protein e.g., SEQ ID NO: 2.

Art Unit: 1639

20. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species below. Applicant must elect one species from each subgroup below. Claim 14 is generic

Subgroup 1: Species of protein library (see claim 14)

Applicant must elect for purposes of search a single species of protein library that is "representative" i.e., contains the same properties and or structural features as the rest of the library members.

Subgroup 2: Species of binding partner (see claim 15)

Applicant must elect for purposes of search a single species of binding partner e.g., biotinylated polynucleotide, polynucleotide without biotinylation, etc..

Subgroup 3: Species of library set (see claim 10)

Applicant must elect for purposes of search a single species of protein e.g. 60 libraries in three groups of 20 libraries with specified amino acids at the -1 and +3 and +6 positions respectively.

Subgroup 4: Species of protein sequence (see claim 12)

Applicant must elect for purposes of search a single species of protein e.g., SEQ ID NO: 2.

Subgroup 5: Species of observation (see claim 19)

Applicant must elect for purposes of search a single species of observation e.g., solid-phase scintillation proximity assay.

21. If applicant elects the invention of Group VI, applicant is required to elect from the following patentably distinct species below. Applicant must elect one species from each subgroup below. Claim 26 is generic

Subgroup 1: Species of gene library (see claim 26)

Art Unit: 1639

Applicant must elect for purposes of search a single species of gene library that is "representative" i.e., contains the same properties and or structural features as the rest of the library members.

Subgroup 2: Species of proteins (see claim 27)

Applicant must elect for purposes of search a single species of protein e.g., zinc fingers.

Subgroup 3: Species of vector (see claim 26)

Applicant must elect for purposes of search a single species of vector.

Subgroup 4: Species of host cell (see claim 27)

Applicant must elect for purposes of search a single species of host cell.

22. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 27 and 28 below).

23. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

24. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or

Art Unit: 1639

(b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

25. In the instant case, the molecules in subgroups 1-4 do not have a common property or significant common structure. Furthermore, the methods for observation require different method steps and different reagents for detection.

For these reasons, election under these rules is proper and required.

26. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

27. Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

28. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1639

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

29. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

30. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.
July 03, 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER